

Category of Food	Maximum Levels in Food (as Served)
Edible plant-based beverages intended as milk alternatives	84 IU/100 g.
Edible plant-based yogurt alternatives	89 IU/100 g.
Soy beverage products	89 IU/100 g
Soy-based butter substitute spreads	330 IU/100 g
Soy-based cheese substitutes and soy-based cheese substitute products	270 IU/100 g

[74 FR 11022, Mar. 16, 2009, as amended at 78 FR 71463, Nov. 29, 2013; 81 FR 46581, July 18, 2016]

§ 172.380 Vitamin D₃.

Vitamin D₃ may be used safely in foods as a nutrient supplement defined under § 170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

(a) Vitamin D₃, also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E)-5,7,10(19)-cholestatrien-3-ol. Vitamin D₃ occurs in and is isolated from fish liver oils. It also is manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol and is purified by crystallization.

(b) Vitamin D₃ meets the specifications of "Vitamin D₃," Food Chemicals Codex, 11th ed., copyright 2018, pp. 1243-1244, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (internet address <http://www.usp.org>). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(c) The additive may be used as follows:

(1) At levels not to exceed 100 International Units (IU) per 240 milliliters (mL) in 100 percent fruit juices (as defined under § 170.3(n)(35) of this chapter) that are fortified with greater than or

equal to 330 milligrams (mg) of calcium per 240 mL, excluding fruit juices that are specially formulated or processed for infants.

(2) At levels not to exceed 100 IU per 240 mL in fruit juice drinks (as defined under § 170.3(n)(35) of this chapter) that are fortified with greater than or equal to 100 mg of calcium per 240 mL, excluding fruit juice drinks that are specially formulated or processed for infants.

(3) At levels not to exceed 140 IU per 240 mL (prepared beverage) in soy-protein based meal replacement beverages (powder or liquid) that are represented for special dietary use in reducing or maintaining body weight in accordance with § 105.66 of this chapter.

(4) At levels not to exceed 100 IU per 40 grams in meal replacement bars or other-type bars that are represented for special dietary use in reducing or maintaining body weight in accordance with § 105.66 of this chapter.

(5) At levels not to exceed 81 IU per 30 grams in cheese and cheese products as defined under § 170.3(n)(5) of this chapter, excluding cottage cheese, ricotta cheese, and hard grating cheeses such as Parmesan and Romano as defined in §§ 133.165 and 133.183 of this chapter, and those defined by standard of identity in § 133.148 of this chapter.

(6) At levels not to exceed 500 IU per 240 mL (prepared beverage) in meal replacement beverages that are not intended for special dietary use in reducing or maintaining body weight and that are represented for use such that the total amount of Vitamin D₃ provided by the product does not exceed 1,000 IU per day.

(7) At levels not to exceed 1.0 IU per kilocalorie in foods represented for use as a sole source of nutrition for enteral feeding.

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(8) At levels not to exceed 84 IU per 100 g (800 IU/quart) in milk that contains more than 42 IU vitamin D per 100 g (400 IU/quart) and that meets the requirements for foods named by use of a nutrient content claim and a standardized term in accordance with § 130.10 of this chapter.

[68 FR 9003, Feb. 27, 2003, as amended at 70 FR 36025, June 22, 2005; 70 FR 37257, June 29, 2005; 70 FR 69438, Nov. 16, 2005; 78 FR 71463, Nov. 29, 2013; 79 FR 46996, Aug. 12, 2014; 81 FR 46582, July 18, 2016; 83 FR 47559, Sept. 20, 2018]

§ 172.381 Vitamin D₂.

Vitamin D₂ bakers yeast may be used safely in foods as a source of vitamin D₂ and as a leavening agent in accordance with the following prescribed conditions:

(a) Vitamin D₂ bakers yeast is the substance produced by exposing bakers yeast (*Saccharomyces cerevisiae*) to ultraviolet light, resulting in the photochemical conversion of endogenous ergosterol in bakers yeast to vitamin D₂ (also known as ergocalciferol or (9,10-seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol)).

(b) Vitamin D₂ bakers yeast may be used alone as an active dry yeast concentrate or in combination with conventional bakers yeast.

(c) The additive may be used in yeast-leavened baked goods and baking mixes and yeast-leavened baked snack foods at levels not to exceed 400 International Units of vitamin D₂ per 100 grams in the finished food.

(d) To assure safe use of the additive, the label or labeling of the food additive container shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (c) of this section.

(e) Labels of manufactured food products containing the additive shall bear, in the ingredient statement, the name of the additive, "vitamin D₂ bakers yeast," in the proper order of decreasing predominance in the finished food.

[77 FR 52231, Aug. 29, 2012]

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§ 172.382 Vitamin D₂ mushroom powder.

Vitamin D₂ mushroom powder may be used safely in foods as a source of vitamin D₂ in accordance with the following prescribed conditions:

(a) Vitamin D₂ mushroom powder is the substance produced by exposing an aqueous homogenate of edible cultivars of *Agaricus bisporus* mushrooms to ultraviolet (UV) light, resulting in the photochemical conversion of endogenous ergosterol in the mushrooms to vitamin D₂ (also known as ergocalciferol or [9,10-Seco(5Z,7E,22E)-5,7,10(19),22-ergostatetraen-3-ol]).

(b) The total dose of UV light applied to the mushroom homogenate shall not exceed 12 Joules/square centimeter (J/cm²).

(c) Vitamin D₂ mushroom powder meets the following specifications:

(1) Moisture, not more than 10 percent.

(2) Negative for *Salmonella*, *Staphylococcus aureus*, and *Listeria monocytogenes*, and any other recognized microbial pathogen or any harmful microbial toxin.

(3) Standard plate count, not more than 5,000 colony forming units per gram (CFU/g).

(4) Yeasts and molds, not more than 100 CFU/g.

(5) Lead, not more than 0.5 milligrams per kilogram (mg/kg).

(6) Arsenic, not more than 0.3 mg/kg.

(d) To assure safe use of the additive, the label or labeling of the food additive container shall bear, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, adequate directions for use to provide a final product that complies with the limitations prescribed in paragraph (f) of this section.

(e) Labels of manufactured food products containing the additive shall bear, in the ingredient statement, the name of the additive "vitamin D₂ mushroom powder," in the proper order of decreasing predominance in the finished food.

(f) Vitamin D₂ mushroom powder may be used as a source of vitamin D₂ in food as follows: